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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No.	:	10/776,635
Applicant	:	John J. ROSSI et al.
Filed	:	12 February 2004
TC/A.U.	:	1635
Examiner	:	Amy Hudson Bowman
Docket No.	:	1954-418
Customer No.	:	06449
Confirmation No.	:	1769

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

In the Office Action mailed 28 June 2005, the Examiner restricted the claims into eight Groups. Applicants provisionally elect Group III (Claims 1, 2, 4, 6-8, 11-22 and 23-25) with traverse. Specifically, Applicants submit that all of the groups should be examined together because the claimed subject matter is directed to any gene of interest and not just to the arbitrary groups set forth by the Examiner and because the claims do not present an undue burden on the Examiner to search them all.

Specifically, Applicants note that the alleged groups set forth by the Examiner are all classified in a single subclass. Thus, there is no multitude of subclasses that would be required to be searched if all of the groups are examined together. In addition, Applicants note that the generic claims are directed to methylating a gene of interest. The gene of interest may include a gene of an infectious agent, such as a viral infectious agent. The gene may also include a cellular gene, such as an RASSF1 gene. Since, the invention relates to the methylation of any gene of interest, all of the groups should be examined together. The invention is the methylation of a gene of interest using an siRNA and is not dependent on a particular gene. Applicants submit that a single search directed to

the methylation of a gene of interest by siRNA will identify prior art directed to methylating both the promoter or the coding sequence. Similarly, such a single search will identify prior art that activates or inactivates the gene of interest upon methylation. Thus, Applicants submit that the restriction between the groups is improper and should be withdrawn.

The Examiner has stated as part of her bases for the restriction is that each of the different target genes have separate nucleotide sequences containing no common core, are directed to different parts of the genes or are directed to the inactivation or activation of the gene. In view of these aspects, the Examiner contends that there would be an undue burden in searching all of the groups. However, Applicants submit that the search and examination of all the groups together would not place a burden on the Examiner that would rise to the level of "undue." Applicants disagree with the Examiner's position that such a search would result in an undue burden on the Examiner despite the fact that all of the groups are classified together. Applicants support their position with the following reasons and arguments set out below.

There are two criteria for a proper requirement for restriction between patentably distinct inventions: 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the Examiner if restriction is not required. See MPEP § 803. Examiners must provide reasons and/or examples to support their conclusions. For purposes of the initial requirement, a serious burden on the Examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by Applicants. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. See MPEP § 803. According to the MPEP, if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction. See MPEP § 803.02.

Concerning the claims of the present application, Applicants agree that the various genes of interest encompassed by the claims may be distinct from each other. However, as stated in the MPEP, as discussed above, distinctness alone is not enough to require a restriction. There must also be a serious burden upon the Examiner. In the absence of such a burden, the Examiner must examine all of the claims. It is urged that the burden of examining all of the genes of interest encompassed by the claims of all of the Groups is not a serious one, and that the burden of examining all of these genes requires no additional searching beyond what the Examiner would have to search in order to examine the provisionally elected claims.

The examination entails various aspects. **First** is a decision concerning utility under 35 U.S.C. §101. Although each gene encompassed by the claims is distinct, they are all related because they are being methylated by the claimed process to either inactivate or active the gene. Consequently, a decision concerning utility will be identical for all of the genes encompassed by the claims, and there is no added burden of examining all of the genes encompassed by the claims as compared to examining only a single class of genes.

The **second aspect** of examination is whether the provisions of the various paragraphs of 35 U.S.C. § 112 have been met. In general, and in this case, this means reviewing the application and claims for compliance with the provisions of paragraphs 1 and 2 of § 112. As for the enablement aspect as found in paragraph 1 of § 112, all of the genes encompassed by the claims are related because they are being methylated by the claimed process to either inactivate or active the gene. Since no basis for distinguishing between the enablement of one gene vs. another gene has been set forth, it is presumed that all of the genes encompassed by the claims will be treated equally. Again, this means that only a single decision needs to be made concerning all of the genes. Therefore, this aspect of the examination will not be a serious burden if all genes encompassed by the claims are examined, vs. only one class of genes.

Concerning paragraph 2 of § 112, this involves the wording of the claims. Any objections to the language of the claims would be the same regardless of which gene was being examined.

Therefore, there is no increase in the burden concerning 35 U.S.C. § 112, second paragraph, if all genes encompassed by the claims are examined.

The **third aspect** of examination is a review of prior art to determine whether the claims are anticipated or obvious. There are two aspects of such a search, which include a review of the prior art literature and patents, as well as a computer search for the relevant claimed method, i.e., a method of methylating a gene of interest. Both the literature to be reviewed and the computer search will be identical for all of the genes encompassed by the claims, i.e., the search will be directed to identifying prior art relating to siRNA directed methylation of a gene of interest, irregardless of whether the methylation is in the promoter or in the coding sequence and irregardless of whether the methylation inactivates or activates the gene of interest. It is the methylation of a gene of interest using siRNA that is being claimed and not a particular sequence of a gene of interest. All of the genes encompassed by this method, although having different nucleotide sequences, have the same utility in the claimed method. Indeed, the Examiner's search for genes encompassed by claim 1 will encompass all genes of interest, and the search will be one search identical for all.

Consequently, it is submitted that the only reason for requiring a selection of a gene or class of genes of interest is because they are distinct from each other. But as explicitly stated in MPEP § 803, the inventions must be distinct and there must be a serious burden on the Examiner. MPEP § 803.02 states that if a search and examination of an entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. As urged above, it is submitted that examination of all of the genes of interest in the context of the claimed invention, i.e., the methylation of the gene of interest by siRNA, will not impose a serious burden.

In view of the above remarks, it is submitted that the restriction is improper because the claimed subject matter is a method for methylating a gene of interest using siRNA and is not a specific sequence. Consequently, it is submitted that all of the subject matter of the claims, i.e., a gene of interest, must be examined because there is no undue burden on the Examiner to examine the claimed method of methylating a gene of interest. Accordingly, it is requested that the

requirement for restriction be reconsidered and withdrawn, and that all of the groups be examined together.

Respectfully submitted,

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